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June 30, 2009

Bruce A. Morrison
US Environmental Protection Agency, Region 7
Mail Code SUPRSPRB
901 North 5th Street
Kansas City, KS 66101

40338414
Superfund

Re: Revised Final Community Risk Assessment, Herculaneum, Missouri

Dear Mr. Morrison:

Enclosed please find the revised and final Community Risk Assessment for Herculaneum, Missouri. This report was revised at US EPA's direction to incorporate the comments received from US EPA, dated March 12, 2009, and from the MDNR/MDHSS, dated May 28, 2009. The table attached to this letter presents a summary of how each comment was addressed. The remainder of this letter provides additional discussion regarding our response to certain of the agencies' requested revisions.

US EPA Comment 45. US EPA initially asked for discussion in the Risk Assessment of the recontamination data, which has been collected since 2001. US EPA's previous comments on the draft Risk Assessment asked for revisions to the discussion of the recontamination data, with which we complied. US EPA is now asking that all discussion of the recontamination data be removed from the Risk Assessment.

Response: We are complying with US EPA's request to remove Section 7.2.7 and Appendix J, which discuss the recontamination data, from the Risk Assessment. However, this revision decreases the value of the final Risk Assessment. It is important to recognize that the recontamination data define baseline conditions in the community at this time, which normally are considered in a risk assessment, and should still be considered in making appropriate risk management decisions in Herculaneum. Doe Run will be submitting to US EPA shortly, under separate cover, a report that summarizes and analyzes the recontamination data, include the most recent data collected in 2009. Now that several years of recontamination data have been collected, analysis shows that US EPA's and the State's earlier conclusions regarding the rate of recontamination and extrapolation of expected future trends overstate the actual rate at which lead concentrations are increasing in soils of nearby properties. We expect this forthcoming report will be critical in making appropriate risk management decisions for the community.

US EPA Comments 32, 33 and 48. US EPA requested in previous comments that the comparison of observed and predicted blood lead levels be removed from the report. MDHSS requested in previous comments that caveats about the comparison be added to the report. As these comments were contradictory, Doe Run chose to respond to the MDHSS comments, which were more consistent with typical risk assessment practices. US EPA now comments again that this comparison between observed and predicted blood lead levels should be removed from the report, and MDHSS comments 12 and 13 state agreement with US EPA's request that the comparison be removed from the report.

Response: The final Risk Assessment includes a summary of the observed blood lead data, but comparison of the observed blood lead data with the blood lead levels predicted by the theoretical models has been removed, as directed by the Agencies. However, we believe that this is an inappropriate revision that 1) leaves unaddressed the obvious question in any reader's mind of how

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the observations and predictions compare, 2) is inconsistent with US EPA guidance, and 3) undermines the value of the Risk Assessment. Consequently, although we are complying with US EPA's directive to remove any comparison from the Risk Assessment, we are enclosing with this letter a "Comparison of Observed and Predicted Blood Lead Levels" that we believe would be relevant for anyone evaluating the Risk Assessment.

We are aware of the descriptions of "well-designed blood lead studies" in both US EPA (1994) and Hogan *et al.* (1998), and we are also aware that MDHSS does not consider its 2001 blood lead sampling in Herculaneum representative of a "study." However, a large number of blood lead samples were taken in Herculaneum, representing a large percentage of the population of young children at the time, and both US EPA and MDNR clearly considered the blood lead results to be sufficiently representative of community-wide exposures in order to drive the risk management decision that led to the Voluntary Property Purchase Agreement. To insist now that this data set has no value in assessing risk in the community is both inconsistent with its prior use and flawed reasoning.

US EPA's 1998 OSWER Guidance Directive "Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA sites and RCRA Corrective Action Facilities" gives the clearest direction on the use of blood lead data and the IEUBK model in risk assessment. Under the general heading "IEUBK and Blood-Lead Studies/Data," the directive states:

> Blood lead data and IEUBK model predictions are expected to show a general concordance for most sites...Where actual blood-lead data varies significantly from IEUBK Model predictions, the model parameters should not automatically be changed. In such a case, the issue should be raised to the Lead Technical Review Workgroup (TRW) to further identify the source of those differences.

Note that this discussion does not refer only to blood lead "studies," but to the broader category of blood lead data. There is an expectation of general concordance between blood lead data and IEUBK model predictions. When there is not general concordance, there should be an attempt to identify the source of those differences. This is exactly what the August 2008 version of the Herculaneum Risk Assessment did. A comparison of observed and predicted blood lead levels was made in order to determine whether or not the expected concordance exists, consistent with this guidance. The Risk Assessment did not propose changes to IEUBK model parameters, consistent with this guidance. The Risk Assessment did identify possible sources of the differences between observed and predicted blood lead, including that the comparisons were not made over identically corresponding geographical areas, and that predictions were made for residences for which no children were included in the blood lead screening program. Again, this step is consistent with guidance. Uncertainties in both the blood lead data and the IEUBK model predictions were discussed in the Risk Assessment, and the potential direction of biases were identified where possible. Removal of this information from the Risk Assessment does not improve the report, but rather gives the appearance that the agencies wish to hide any discordance between data and prediction and any sources of uncertainty. These sources of uncertainty exist whether they are discussed or not.

Therefore, to comply with the agencies' directives and yet ensure that this information is not lost, we reproduce the discussion of observed and predicted blood lead levels as an attachment to this cover letter.

Sincerely,

GRADIENT CORPORATION

Teresa S. Bowers

Teresa S. Bowers, Ph.D.
Principal

Enclosures

1 Comparison of Observed and Predicted Blood Lead Levels

The information provided here is taken from an earlier draft version of the Community Risk Assessment for Herculaneum, Missouri (August 13, 2008). This text has been removed from the final version of the Risk Assessment at the directive of the EPA and MDNR/MDHSS.

1.1 Blood Lead Levels for Young Children

Several blood lead studies and screening programs for young children have been conducted in Herculaneum. Studies conducted by Doe Run in 1975, 1984, 1992 and 2000 of children under the age of five years (1975, 1984) or seven years (1992, 2000) showed decreasing blood lead levels with time (see Table 1) (Phillips *et al.*, 1989; Doe Run and JCHD, 2000).

Table 1
Blood Lead Levels (μg/dL)

	Herculaneum		Control Community		
	Sample Size	Arithmetic Mean	Sample Size	Arithmetic Mean	Community
1975	53	24.3	85	16/7	Perryville
1984	129	16.5	100	9.9	Festus
1992	NA	11.6	NA	7.6	NA
2000	60	7.5	NA	4.2	Pevely/Crystal Heights

NA: Not available.

Blood lead data were also collected by the Missouri Department of Health and Senior Services (MDHSS) in cooperation with ATSDR. Between June 1992 and May 1999, 52 children (age range not identified) were tested, of which 37 had blood lead levels below 10 μg/dL, 12 had blood lead levels between 10 and 20 μg/dL, and 3 had blood lead levels above 20 μg/dL (ATSDR, 2001).

In 2001, MDHSS and ATSDR conducted a screening program in which they tested 118 children under the age of 7 years, of which 85 had blood lead levels below 10 μg/dL, 27 had blood lead levels between 10 and 20 μg/dL, and six had blood lead levels above 20 μg/dL (ATSDR and MDHSS, 2002). Results were reported on a geographic basis, and showed a higher prevalence of elevated blood lead levels in areas that are closer to the facility.

From 1993 to 2007, MDHSS collected blood lead data for children in Herculaneum. As shown in Table 2, the highest geometric mean blood lead level of 13.3 μg/dL was observed in 1998. Since that time, the geometric mean blood lead level has decreased each year to 2.2 μg/dL in 2007. From 2004 to 2007, no children were reported with blood leads greater than 10 μg/dL.

Table 2
MDHSS Blood Lead Summary Statistics for Children (0 to 84 Months)
Herculaneum, Missouri

Year	Number of Children Tested	Minimum PbB (μg/dL)	Maximum PbB (μg/dL)	Arithmetic Mean PbB (μg/dL)	Geometric Mean PbB (μg/dL)	Number of Children with PbB > 10 μg/dL	Percent of Children with PbB > 10 μg/dL
1993	7	2.0	25.0	13.0	10.1	5	71%
1994	13	2.0	20.5	12.4	10.4	8	62%
1995	13	6.0	20.8	13.8	13.0	9	69%
1996	12	5.0	21.0	13.8	12.8	10	83%
1997	14	1.0	20.3	10.5	8.1	7	50%
1998	5	9.0	21.0	13.9	13.3	4	80%
1999	9	3.0	20.0	10.7	9.3	4	44%
2000	57	1.0	35.6	7.4	5.9	9	16%
2001	140	2.0	24.8	7.0	5.6	29	21%
2002	77	1.0	21.7	6.0	5.0	8	10%
2003	17	1.0	10.5	5.1	4.2	1	6%
2004	34	1.0	8.0	3.3	2.7	0	0%
2005	26	1.5	9.0	2.6	2.2	0	0%
2006	38	0.5	8.0	2.7	2.1	0	0%
2007	34	0.5	9.0	2.8	2.2	0	0%

Data restricted to children aged 0-84 months at the time of PbB collection.
If multiple PbB samples were available for a child within a given year, the mean PbB value across samples was used.

Typically in a lead risk assessment one would pair the blood lead data with the environmental data on a residence-specific basis in order to compare the IEUBK model predicted blood lead levels with the measured blood lead levels. US EPA guidance states that such comparisons between predicted and observed data are appropriate (US EPA, 1998a; 1994b) under circumstances where the blood lead studies are well-conducted[1] and thought to be representative of the community. This risk assessment can not perform residence specific comparisons because the necessary geographic information for the blood lead measurements has not been made available. However, we can compare the observed and predicted blood lead levels on a broader geographic basis. The 2001 MDHSS/ATSDR screening program reports the total number of blood lead measurements and the number of blood lead levels above 10 μg/dL in ¼-mile concentric rings centered on the facility stack. The ¼- and ½-mile rings correspond approximately to the

[1] See US EPA 1998a and 1994b for detailed definitions of "well-conducted" studies.

area included in EAs 1 and 2 in this risk assessment. The ¾- and 1-mile rings correspond approximately to EAs 3, 4, and 5. Table 3 shows a comparison of the predicted and observed percentage of elevated blood lead levels for the corresponding MDHSS/ATSDR concentric rings and EAs defined in this risk assessment. We are unable to compare mean predicted and observed blood lead levels for children because mean values were not made available by MDHSS/ATSDR.

Table 3
Comparison of Predicted and Observed Blood Lead Levels in Young Children

	Predicted Blood Lead Levels		2001 Observed Blood Lead Levels	
EA	N (properties)	Average % >10 µg/dL	N (children with measured blood leads)	% > 10 µg/dL
1A	108	60	32	53
2A	42	81		
3	47	34	39	31
4	83	43		
5	31	11		

This comparison shows that the percent of blood lead levels that are predicted to be above 10 µg/dL is somewhat higher than actually observed. The IEUBK model predicts that 60 and 81% of children living in EAs 1 and 2 would have elevated blood lead levels while the 2001 screening program shows 53% elevated PbB within ½ mile of the facility. The IEUBK model predicts that 34, 43, and 11% of children living in EAs 3, 4, and 5 would have elevated blood lead levels, respectively, while the 2001 screening program shows 31% elevated PbB between ½ mile and 1 mile of the facility. These comparisons are only approximate because the geographic areas do not correspond exactly and the risk assessment predicts blood lead levels for many properties, while children in the blood lead screening program reside at only a fraction of these properties.

The model predictions and measured observations contain a number of limitations that qualify the differences noted. The results of blood lead modeling should be interpreted as probabilities rather than certainties, as model predictions are based on hypothetical receptors employing a number of input assumptions, and therefore, cannot be expected to directly correspond to observed results. In addition, the blood lead testing conducted in Herculaneum was voluntary and is not necessarily a representative sample of the entire community. Also, observed blood lead levels could be affected by community awareness and intervention efforts.

The comparison between predicted and observed BLL is further complicated by the fact that the 2001 blood lead screening program was completed before the most recent air controls were implemented.

The air lead levels in the 2001 screening program would correspond approximately to the air lead levels described as pre-SIP in this risk assessment, whereas the IEUBK model predictions were based on 2007 SIP modeled air lead levels. If the IEUBK model were run using the pre-SIP air lead levels, the model predictions would be slightly higher than those shown in Table 3; thus the model over-predictions would be greater. This fact, combined with the lack of reported blood lead levels above 10 μg/dL since 2004, suggests that the IEUBK model may be over-predicting the effects of exposure of young children to current environmental conditions in Herculaneum.

1.2 Blood Lead Levels for Adults

In 2001, MDHSS and ATSDR also tested 162 adolescents between ages 6 and 17 years, and 655 adults 18 years and older (ATSDR and MDHSS, 2002). Thirteen adolescents, or 8%, had blood lead levels above 10 μg/dL. Two adults had blood lead levels above 25 μg/dL. From these groups there were 197 women between ages 15 and 44 years, with an average blood lead of 3.4 μg/dL. Only one woman had a blood lead level above 10 μg/dL. Data were reported for a subgroup of adults over the age of 65 years as well The average blood lead level of these 166 adults was 5.9 μg/dL, of which 21, or approximately 13%, had blood lead levels above 10 μg/dL.

This risk assessment predicts that blood lead levels for adults living within the area of the 2001 blood lead screening program will have an average geometric mean ranging from 3.3 to 15.0 μg/dL for EAs 5 and 2A, respectively, with predicted percentages of blood lead levels above 10 μg/dL ranging from 3.7 to 47%. These predicted blood lead levels are considerably higher than those found for women of child-bearing age in the 2001 screening program. Observed blood lead levels in adults over the age of 65 years are somewhat similar to predicted blood lead levels outside of EAs 1 and 2. However, blood lead levels in older adults are significantly influenced by cumulative body burden, which can be more important than current exposures. The ALM addresses cumulative body burden by using a baseline blood lead level, which in this risk assessment corresponds to national averages for women of child-bearing age. Therefore, we would not expect the predicted blood lead levels here to reflect cumulative exposures in older adults. The comparison of the ALM predictions to observed blood lead levels in women of child-bearing age, the primary adult population of concern, suggests that the ALM is overestimating environmental lead risks to adults in this area. This comparison is subject to many of the same uncertainties described above for the comparison of observed and predicted blood lead levels for children. These include the fact that the blood lead testing was voluntary and is not necessarily representative of the entire community, it is possible that adult blood lead levels are affected by community awareness and intervention efforts, and the modeled results are based on hypothetical receptors and should be interpreted as probabilities rather than certainties.

1.3 Summary and Conclusions

A comparison of observed and predicted blood lead levels for general areas of Herculaneum indicates that both the IEUBK model and the Adult Lead Model may be over-predicting lead risks. The IEUBK model over-predicts the percent of children with blood lead levels above 10 µg/dL, and these over-predictions would be even greater if the modeling were done with pre-SIP data that is representative of the time period during which the blood lead data were collected. In addition, there have been no reported blood lead levels above 10 µg/dL in children since 2003. These points suggest that the IEUBK model may be over-predicting the effects of exposure of young children to current environmental conditions in Herculaneum. The predicted blood lead levels for adults are considerably higher than those found for women of child-bearing age in the 2001 study screening conducted by MDHSS and ATSDR, suggesting that the Adult Lead Model is overestimating environmental lead risks to adults in this area. The 2001 screening, included 197 women between the ages of 15 and 44 years, with an average blood lead of 3.4 µg/dL, and only one woman had a blood lead level above 10 µg/dL. However, for adults in EAs 1A, 1B, 2A, and 2B, the predicted average geomean blood leads range from 6.1 to 15 µg/dL, and the modeled exceedance probabilities range from 17 to 47%. The comparison of predicted and observed blood leads includes a number of limitations. Blood lead model predictions are based on hypothetical receptors employing a number of input assumptions, therefore, they cannot be expected to directly correspond to observed results, and should be interpreted as probabilities rather than certainties. In addition, the blood lead testing conducted in Herculaneum was voluntary and is not necessarily a representative sample of the entire community. Also, observed blood lead levels could be affected by community awareness and intervention efforts. Nevertheless, the comparisons presented here combined with the large number of participants in the voluntary screening programs suggest that the models are over-predicting lead risks in the community.